REMARKS

This amendment responds to the Office Action dated June 21, 2005. At that time, the pending claims were 1, 8-14. Claims 1, 8, 10-14 have been canceled; claim 9 has been amended to narrow its scope to a controlled-release dosage form of venlafaxine or its pharmaceutically acceptable salts; and claim 15 has been added to claim a sustained-release dosage form.

Applicant brings the Examiner's attention to the decision of the Board of Appeals mailed October 26, 2005 (a copy of which is enclosed) in connection with related application Serial No. 08/442,292.

Applicant respectfully requests examination of the claims as amended in light of all of the evidence of record.

Respectfully submitted,

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DAVID E. EDGREN, GURDISH K. BHATTI, ZAHEDEH HATAMKHANI, and PATRICK S.L. WONG

Appeal No. 2005-1829
Application No. 08/442,292

ON BRIEF

Before WILLIAM F. SMITH, ELLIS, and SCHEINER, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 6 and 7, the only claims remaining in the application.

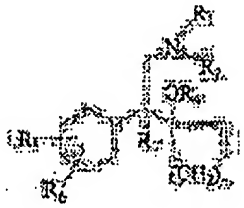
Claim 6 is representative of the subject matter on appeal and reads as follows:

6. A dosage form for the oral delivery of a drug to an environment of use, wherein the dosage form comprises:

(a) a wall comprising at least in part a composition permeable to the passage of fluid, which wall surrounds:

(b) a compartment;

(c) a drug composition in the compartment comprising a drug of the formula:



wherein the dotted line represents a member selected from the group consisting of an unsaturation and cycloalkenyl group; R_1 is a member selected from the group consisting of hydrogen and alkyl of 1 to 6 carbon atoms; R_2 is a member selected from the group consisting of hydrogen and alkyl of 1 to 6 carbon atoms; R_4 is a member selected from the group consisting of hydrogen, alkyl of 1 to 6 carbon atoms, formyl, and alkanoyl of 2 to 7 carbon atoms; R_5 and R_6 are independently a member selected from the group consisting of hydrogen, hydroxyl and alkyl of 1 to 6 carbon atoms; alkoxy of 1 to 6 carbon atoms, alknaoyloxy of 2 to 7 carbon atoms, nitro, alkylmercapto of 1 to 6 carbon atoms, amino, alkylamino of 1 to 6 carbon atoms, alkanamido of 2 to 7 carbon atoms, halo and trifluoroethyl; R_7 is a member selected from the group consisting of hydrogen and alkyl of 1 to 6 carbons; an n is 0 to 4; and

(d) a displacement in the compartment comprising a composition comprising an osmotically active compound; and,

(e) an exit passageway in the dosage form for delivering the drug composition form the dosage form.

Claims 6 and 7 stand rejected under 35 U.S.C. § 103(a) with the examiner relying upon Husbands[1] and Theeuwes[2] as evidence of obviousness. We affirm.

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[1] U.S. Patent No. 4,761,501, issued August 2, 1988

[2] U.S. Patent No. 4,111,201, issued September 5, 1978

Discussion

We initially note that appellants state that claims 6 and 7 are grouped together for the purpose of this appeal. Appellants' Brief received December 18, 2003, page 4 (Appeal Brief). Thus, we will limit our consideration of the issues raised in this appeal as they pertain to claim 6. See the then-existing provisions of 37 CFR § 1.192(c)(7).

As seen, claim 6 is directed to a dosage form comprising a wall, a compartment, a specified drug composition in the compartment, a displacement in the compartment that includes an osmotically active compound, and an exit passageway for delivering the drug composition from the dosage form. There is no dispute on this record as to the examiner's fact finding in regard to the specific teachings of Husbands and Theeuwes. Appellants do not dispute that Husbands teaches the genus of compounds required by claim 6(c) and their utility as antidepressants. See, e.g., the abstract of Husbands. Nor do appellants dispute the examiner's finding that Theeuwes describes a dosage form comprising a wall, a compartment, a drug composition in the compartment that may be an antidepressant, a displacement in the compartment that includes a composition comprising of an osmotically active compound, and an exit passageway in the dosage form for delivering the drug composition from the dosage form. See, e.g., Theeuwes, column 4, line 3 - column 5, line 36; column 10, line 22.

In other words, Husbands and Theeuwes teach each of the elements required by claim 6 on appeal. Thus, the question becomes whether a person of ordinary skill in the art would have had a reason, suggestion, or motivation to combine the teachings of the two references in order to arrive at the subject matter of claim 6 as a whole. Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996). We agree with the examiner that the requisite reason, suggestion, or motivation exists.

We find the requisite reason, suggestion, or motivation from the disclosure in Theeuwes that the described dosage form provides for "the controlled and continuous delivery of an active agent over a prolonged period of time which system overcomes the problems known to the prior art." Column 2, lines 16-20. We also point to the disclosure in Theeuwes stating:

> Yet [still] a further object of the invention is to provide an osmotic therapeutic system that can administer a complete pharmaceutical regimen comprising soluble to very soluble or limited soluble to practically insoluble agents at a constant rate to animals including warm blooded animals and humans for a particular time period, the use of which requires intervention only for initiation and possibly termination of the regimen.

Id., column 2, lines 39-46.

Since Theeuwes describes antidepressants as one of the active agents useful in the dosage form of that invention, we agree with the examiner's conclusion that it would

have been prima facie obvious to a person of ordinary skill in the art to formulate the antidepressants described in Husbands in the manner described in Theeuwes in order to arrive at an extended/controlled release formulation of that active agent.

We have considered the arguments set forth in the Appeal Brief but do not find them convincing. Appellants first argue on pages 4-7 of the Appeal Brief that the examiner had "misstated" the disclosure of Theeuwes and that the examiner does not "cite any part of [Theeuwes], or any other evidence for that matter, to show that the art recognized 'delivery at a controlled rate' as the beneficial effect sought." The examiner did point to column 2, lines 16-20 of Theeuwes where it states that the dosage form of that reference provides for the "controlled and continuous delivery of an active agent over a prolonged period of time." Examiner's Answer, page 4.

Appellants argue on pages 7-9 of the Appeal Brief that the examiner has not established the requisite reason, suggestion, or motivation. As set forth above, we have found that a consideration of Husbands and Theeuwes together provides this element of the obviousness inquiry.

Appellants argue on pages 9-10 that "there is simply no teaching, suggestion or reason in [Husbands] to incorporate venlafaxine into a controlled-release dosage form." We might agree with this argument if the only evidence relied upon by the examiner in formulating the obviousness rejection was Husbands. However, the examiner relies

upon the combined disclosures of Husbands and Theeuwes. As pointed out above, Theeuwes amply sets forth the reasons why a person of ordinary skill in the art would have found it obvious to formulate antidepressants such as those described in Husbands into a controlled release form as required by claim 6 on appeal.

Appellants next argue on pages 10-12 of the Appeal Brief that the mention of antidepressants in Theeuwes does not provide motivation. In making this argument, appellants make reference to a remand a merits panel of this Board made in a different appeal, Appeal No. 1996-3159, where a different Theeuwes reference was applied under 35 U.S.C. § 102. Suffice it to say, what a merits panel may have said in regard to a different Theeuwes reference applied under 35 U.S.C. § 102 in another appeal has little if any relevance in considering a § 103 rejection based upon this Theeuwes reference in combination with Husbands. Thus, appellants' arguments in this regard are not relevant.

Finally, appellants argue on pages 12-13 of the Appeal Brief that the unique properties of venlafaxine support patentability. Since claim 6 on appeal is not limited to the single species venlafaxine, appellants' arguments in this regard are not commensurate in scope with the claim under consideration.

We have also considered the Reply Brief submitted by appellants on July 6, 2004. We find that appellants renew their arguments concerning venlafaxine's unique

properties on pages 2-3 of the Reply Brief. Again, those arguments are not commensurate in scope with claim 6 on appeal.

Appellants also renew their arguments concerning the requisite reason, suggestion, or motivation for combining the references on pages 4-7 of the Reply Brief. We point to our analysis above, where we have found the combined disclosures of Husbands and Theeuwes provide ample reason, suggestion, or motivation to combine their teachings in a manner required in order to arrive at the subject matter of claim 6 on appeal as a whole.

The decision of the examiner is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Joan Ellis
Administrative Patent Judge

Toni R. Scheiner
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

Appeal No. 2005-1829
Application 08/442,292

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